

Patent claims

1. The use of magnesium stearate in dry powder formulations for inhalation, comprising a
5 pharmaceutically inactive carrier of noninhalable particle size and a finely divided pharmaceutically active compound of inhalable particle size, to improve the resistance to moisture.
2. The use of magnesium stearate in dry powder
10 formulations for inhalation, comprising a pharmaceutically inactive carrier of noninhalable particle size and a finely divided pharmaceutically active compound of inhalable particle size, to reduce the influence of penetrating moisture on the fine
15 particle fraction (FPF).
3. The use as claimed in claim 1 or 2, wherein the pharmaceutically inactive carrier, the finely divided active compound and the magnesium stearate are present in the form of an interactive mixture.
- 20 4. The use as claimed in any one of claims 1 to 3, wherein the magnesium stearate is employed in a concentration of 0.1 to 2% by weight, based on the total formulation.
5. The use as claimed in any one of claims 1 to 4,
25 wherein the magnesium stearate is employed in a concentration of 0.25 to 1% by weight, preferably 0.4 to 0.8% by weight, based on the total formulation.
6. The use as claimed in any one of claims 1 to 5,
30 wherein the combination of active compound and carrier has a high sensitivity to the influence of atmospheric humidity.
7. The use as claimed in any one of claims 1 to 6,
wherein the dry powder formulation contains, as
35 pharmaceutically active compound, a beta-mimetic, an anticholinergic, a corticosteroid, a leukotriene antagonist, a phosphodiesterase inhibitor, a PAF inhibitor, a potassium channel opener, a painkiller, a

potency agent, a peptide or a protein, preferably a beta-mimetic and/or an anticholinergic and/or a corticosteroid.

8. The use as claimed in any one of claims 1 to 7,
5 wherein the dry powder formulation contains, as pharmaceutically active compound, a beta-mimetic from the group comprising levalbuterol, terbutaline, reproterol, salbutamol, salmeterol, formoterol, fenoterol, clenbuterol, bambuterol, tulobuterol,
10 broxaterol, epinephrine, isoprenaline or hexoprenaline, an anticholinergic from the group comprising tiotropium, ipratropium, oxitropium or glycopyrronium, a corticosteroid from the group comprising butoxicart, rofleponide, budesonide, ciclesonide, mometasone,
15 fluticasone, beclomethasone, loteprednol or triamcinolone, a leukotriene antagonist from the group comprising andolast, iralukast, pranlukast, imitroast, seratrodast, zileuton, zafirlukast or montelukast, a phosphodiesterase inhibitor from the group comprising
20 filaminast and piclamilast, a PAF inhibitor from the group comprising apafant, forapafant and israpafant, a potassium channel opener from the group comprising amiloride and furosemide, a painkiller from the group comprising morphine, fentanyl, pentazocine,
25 buprenorphine, pethidine, tilidine, methadone or heroin, a potency agent from the group comprising sildenafil, alprostadil and phentolamine, a peptide or protein from the group comprising insulin, erythropoietin, gonadotropin or vasopressin, or a
30 pharmaceutically acceptable derivative or salt of one of these compounds.

9. The use as claimed in any one of claims 1 to 8, wherein the dry powder formulation contains, as pharmaceutically active compound, a beta-mimetic from
35 the group comprising levalbuterol, salbutamol, salmeterol, formoterol, fenoterol, clenbuterol, bambuterol, tulobuterol, broxaterol, epinephrine, isoprenaline and hexoprenaline, an anticholinergic from

the group comprising tiotropium, ipratropium, oxitropium and glycopyrronium, a corticosteroid from the group comprising budesonide, ciclesonide, mometasone, fluticasone, beclomethasone, loteprednol
5 and triamcinolone, a leukotriene antagonist from the group comprising zileuton, zafirlukast and montelukast, a potassium channel opener from the group comprising amiloride and furosemide, a painkiller from the group comprising morphine, fentanyl, pentazocine,
10 buprenorphine, pethidine, tilidine, methadone and heroin, a potency agent from the group comprising sildenafil, alprostadil and phentolamine, a peptide or protein from the group comprising insulin, erythropoietin, gonadotropin and vasopressin, or a
15 pharmaceutically acceptable derivative or salt of one of these compounds.

10. The use as claimed in any one of claims 1 to 9, wherein the dry powder formulation contains a pharmaceutically active compound which is present in
20 the form of a pharmaceutically acceptable salt or ester.

11. The use as claimed in any one of claims 1 to 10, wherein the dry powder formulation contains, as pharmaceutically active compound, a beta-mimetic and/or
25 an anticholinergic and/or a corticosteroid, which is present in the form of a pharmaceutically acceptable salt or ester.

12. The use as claimed in any one of claims 1 to 11, wherein the dry powder formulation contains, as
30 pharmaceutically active compound, a beta-mimetic from the group comprising levalbuterol sulfate, formoterol fumarate, formoterol tartrate, salbutamol sulfate and salmeterol xinafoate and/or an anticholinergic from the group comprising oxitropium bromide, glycopyrrolate,
35 ipratropium bromide and tiotropium bromide.

13. The use as claimed in any one of claims 1 to 12, wherein the dry powder formulation contains, as

pharmaceutically active compound, formoterol or a pharmaceutically acceptable salt thereof.

14. The use as claimed in any one of claims 1 to 13, wherein the dry powder formulation contains, as
5 pharmaceutically active compound, a corticosteroid from the group comprising beclomethasone dipropionate, fluticasone propionate, triamcinolone 16,21-diacetate, triamcinolone acetonide 21-acetate, triamcinolone
10 acetonide 21-disodium phosphate, triamcinolone acetonide 21-hemisuccinate, mometasone furoate and loteprednol etabonate.

15. The use as claimed in any one of claims 1 to 14, wherein the dry powder formulation contains, as
15 pharmaceutically active compound, a corticosteroid in combination with a beta-mimetic, preferably a corticosteroid, from the group comprising ciclesonide, rofleponide, fluticasone propionate, mometasone furoate and loteprednol etabonate, in combination with a beta-
20 mimetic from the group comprising formoterol fumarate, formoterol tartrate, levalbuterol sulfate and salmeterol xinafoate.

16. The use as claimed in any one of claims 1 to 15, wherein the dry powder formulation contains, as
25 carrier, a mono- or disaccharide, a sugar alcohol, polylactic acid or cyclodextrin.

17. The use as claimed in any one of claims 1 to 16, wherein the dry powder formulation contains, as
carrier, glucose, lactose monohydrate or trehalose.

18. The use as claimed in any one of claims 1 to 17, wherein a pharmaceutically inactive carrier of
30 noninhalable particle size, a finely divided pharmaceutically active compound of inhalable particle size and magnesium stearate are mixed with one another.

19. The use as claimed in claim 18, wherein a
35 preliminary mixture of magnesium stearate with the carrier is prepared and then the active compound is admixed.

20. The use as claimed in claim 18, wherein a preliminary mixture of the active compound with the carrier is prepared and then the magnesium stearate is admixed.
- 5 21. The use as claimed in any one of claims 1 to 20, for use in a dry powder inhaler, preferably a multi-dose dry powder inhaler, which contains a powder reservoir.